



Laboratory Audits Conducted by PPD

PPD is contracted by the Division of AIDS (DAIDS) to perform laboratory audits for Good Clinical Laboratory Practice (GCLP) compliance throughout the world. The DAIDS laboratory program staff is responsible for requesting audits. These audits may be triggered due to an immediate need, or may be driven by an established audit visit schedule. PPD auditors will contact the site staff to schedule the dates for the audit. An e-mail is then sent to the site to introduce the auditor and confirm the audit dates. After dates are set, a pre-visit letter is provided 10 to 15 business days prior to the audit date, which describes the agenda for the visit. In addition, a copy of the appropriate audit checklist will be provided with the pre-visit letter.

The types of audits performed by PPD include: General Laboratory, Central/Endpoint Laboratory, Peripheral Blood Mononuclear Cell (PBMC) Processing Laboratory, and Specimen Repository audits. The customized laboratory audit checklists utilized for each of these audits were developed using Good Clinical Laboratory Practice (GCLP) standards and cover regulations from 21 CFR Part 58 (GLP) and 42 CFR Part 493 (CLIA), and are augmented by guidelines from the Clinical Laboratory Standards Institute, the College of American Pathologists, and the International Organization for Standardization. The checklists take approximately three working days for a laboratory auditor to complete during the audit visit. The following GCLP Principles are covered, as applicable, in each document:

- External Quality Assurance
- Organization and Personnel
- Equipment
- Testing Facilities Operation
- Test and Control Articles
- Verification of Performance Specifications
- Records and Reports
- Physical Facilities
- Specimen Transport and Management
- Personnel Safety
- Laboratory Information Systems
- Quality Management

In addition, an audit of practice versus procedure is covered during each audit visit. This exercise evaluates the accuracy of a particular laboratory in following their established standard operating procedure (SOP) for a particular assay that the auditor selects at the time of the visit. When the audit visit is completed, a report is sent to the appropriate DAIDS program staff member within 20 business days. Distribution of the reports to the sites and other interested parties is determined by the distribution list provided to PPD by DAIDS. The resolution of identified deficiencies found during the audit is then conducted between the site and the DAIDS Laboratory Program staff.

Laboratory Audit Checklists

There are four different checklists that are used by PPD laboratory auditors.

All four of the checklists are similar in that they cover the same GCLP principles consistently for each facility type. This construction is in place to assist in the ongoing efforts to establish a global GCLP standard for all DAIDS-funded laboratories. To that end, there are subtle differences to be noted. These differences are due to the distinct variation in the scope of services provided by each laboratory type. A summary of each audit approach is listed and found along with the corresponding checklists below.

General Laboratory

The General Laboratory Checklist was developed mainly for safety laboratories. This checklist is used globally for clinical trial site-operated, contracted, satellite, and back-up laboratories. It incorporates all of the aforementioned GCLP principles and requires the auditor to address each principle for all testing activities funded by the DAIDS.

PBMC Laboratory

The PBMC Laboratory Checklist is tailored specifically for processing laboratories that work with PBMC. The questions are focused on all phases of PBMC testing, with a section dedicated to evaluating the actual performance of the PBMC processing steps versus the approved standard operating procedure.

Central Laboratory

The Central Laboratory Checklist is specific for laboratories performing endpoint assays, including non-FDA approved methods. The general checklist questions, as with all the checklists, are included as applicable along with specific topics related to endpoint testing.

Specimen Repository

The specimen repository checklist is unique; although all applicable GCLP principles are covered, the focus is placed on specimen tracking and storage. The auditor is required to report more comprehensively in these areas. For example, in the other laboratory checklists, 5 to 10 random specimens are required to be audited from reception to final disposition. In this checklist, 1000 randomly selected specimens will undergo this type of audit. This audit requires completion by at least two auditors in the targeted time period of three working days.

Distribution of Audit Reports and Resolution

The final version of the lab audit report will be issued 20 business days from the end date of the audit to the DAIDS. Once distributed, the DAIDS staff will request a response from the site staff at a time deemed reasonable by the DAIDS. The expectation is that the site staff will respond to any items in the report deemed to need corrective action by the site staff. The DAIDS will evaluate the response, including any corrective and preventative action (CAPA) measures, as applicable. If the DAIDS staff find the response or CAPA to be inadequate upon review, additional guidance may be given with a second response required from the site staff. This process will continue until the DAIDS staff is satisfied that all inadequacies have been addressed, and will then communicate with the site that the audit report has been resolved.